



## Iatrogenic vCJD from surgical instruments

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BMJ 2001;322:1558-1559

doi:10.1136/bmj.322.7302.1558

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much remains to be done merely to catch up with fields such as cancer, cardiovascular disease, and infection.

Lack of data is not the sole cause of patchy and often ineffectual efforts to prevent injury. Pless has highlighted a paradox: preventive efforts are often directed at diseases for which the means of prevention are of doubtful efficacy, while other conditions (including injuries) for which effective preventive measures are available are often ignored.<sup>5</sup> Possible reasons include ignorance of the scale of the problem, the mistaken perception that many injuries are "accidental" and therefore unavoidable, the belief that prevention lies outwith the scope of health services, and an absence of political will.

In the end, effective injury prevention requires the wholehearted commitment of governments. Taking a lead from Sweden, the US, Australasia, and parts of Europe have recently pushed injuries higher up the political agenda.<sup>6</sup> This has been achieved through political lobbying and seeking support from non-governmental sources, including the private and voluntary sectors. The publication of *Injury in America* in 1985 was widely regarded as a turning point in the US<sup>10</sup> and was followed by a surge in funding for injury research and prevention. In 1999 the European Union launched an injury prevention programme, and the World Health Organization has played a part in keeping injury and violence prevention high on the international agenda ([www.who.int/violence\\_injury\\_prevention/](http://www.who.int/violence_injury_prevention/)).

In contrast, the United Kingdom lags behind in its response to injuries. Although "accidents" have been a stated public health priority since the early 1990s, government commitment to injury prevention has been strong on rhetoric and weak on action. The UK compares well with other European countries in that it has the second lowest overall child injury death rate (after Sweden). These figures, however, conceal a poorer record on specific causes such as pedestrian injuries.<sup>11</sup> Moreover, deaths are merely the tip of an injury iceberg that is largely invisible because of the lack of data on incidence, morbidity, and disability.

The political inertia in the UK was challenged in 1998 by a report, *Action on Injury*, published with the help of the Department of Health as a supplement to the journal *Injury Prevention* and supported by a national conference.<sup>12</sup> The report was the initiative of a small group of activists working with the relevant royal colleges and faculties and the Child Accident Prevention Trust. Its aim was to raise the profile of

injury prevention in the UK, and there is some evidence that it succeeded. For example, the white paper on public health in England, published in 1999,<sup>13</sup> emphasises the need to reduce injuries and accepts that responsibility for strategic leadership lies with the health departments. These developments—along with the Department of Health's recently established task force for England—have heartened the injury prevention community, but they are only a start.

Further progress in the UK will depend mainly on four key measures: the creation of a dedicated agency to implement injury prevention and control programmes, improved injury surveillance, the encouragement of multidisciplinary research, and coordinated multi-sectoral action at local and national levels. Unless the UK acts to prevent injuries, more avoidable death and disability will be the inevitable consequence.

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## Iatrogenic vCJD from surgical instruments

*The risk is unknown, but improved decontamination will help reduce the risk*

Because of fears about iatrogenic transmission of new variant Creutzfeldt-Jakob disease (vCJD), the Department of Health recently announced fundamental changes in surgical practice, and in particular the practice of ear, nose, and throat surgery. Decontamination facilities in hospitals are to be upgraded, and by the end of 2001 all adenotonsillectomy procedures will be performed using disposable instruments.<sup>1</sup> Why are these measures necessary?

At present both the prevalence of subclinical vCJD and its degree of infectivity via surgical instruments are unknown. Also, no cases of iatrogenic vCJD in humans have so far been identified. Nevertheless, based on the evidence we do have, we can make judgments about the features that are likely to affect the size of the risk from surgical instruments.

So far the disease marker (and likely transmissible agent) for vCJD (PrP<sup>Sc</sup>) has been identified by sensitive

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western blot techniques in the neural and lymphoreticular tissues of brain, tonsil, and spleen.<sup>2</sup> A positive appendix (which consists largely of lymphoreticular tissue) has not yet been reported using this technique, though one archived appendix has been reported to be positive using immunohistochemical staining.<sup>3</sup>

There is clear evidence from case reports in humans and animal models that prion diseases can be transmitted via stainless steel instruments.<sup>4,5</sup> Also the infective agent of iatrogenic prion diseases has shown remarkable resistance to the conventional sterilisation techniques used for surgical instruments.<sup>6</sup> The incubation period of vCJD is unknown but could be several decades,<sup>7</sup> so it is therefore unlikely that any iatrogenic cases will have yet emerged. The precautionary principle suggests that when the potential risk to public health is substantial there is no case for sitting back to wait for indisputable evidence. This view has influenced the British government's previous decision to leucodeplete all blood and blood products.<sup>8</sup>

So what is the purpose of the new policy to upgrade decontamination facilities?

The most effective generic approach to preventing vCJD transmission is thought to be to remove all traces of organic material at the washing phase of the decontamination process (washing, disinfection, and sterilisation).<sup>9</sup> Some decontamination facilities in British hospitals are relatively old, and upgrading them should enable more effective decontamination. This should reduce the risk of transmission of vCJD and of other (including unknown) diseases. Measures are also being introduced to enable all reusable surgical instrument sets to be traced.<sup>10</sup>

Why won't these general measures do for adenotonsillectomy and why must this procedure, specifically, be performed with disposable instruments? We know through animal models that PrP<sup>Sc</sup> becomes positive in lymphoreticular tissues relatively early in the incubation period.<sup>11</sup> The population undergoing adenotonsillectomy is young (median age 9 years) and has a further life expectancy of about 65 years. Even if vCJD has an incubation period of several decades, the potential impact of iatrogenic transmission to children is particularly serious. Tonsillectomy and adenoidectomy are common operations (about 69 000 were performed in the UK in 1999–2001<sup>12</sup>). The instrument sets are reused often, and their time in service often exceeds 10 years. Therefore, each set of instruments will over its lifetime have come into contact with many patients, significantly increasing the risk of contamination. In this situation, even if the relative risk is low, the population attributable risk is probably high. This attributable risk reflects the potential numbers of patients who could be affected. If the prevalence of preclinical disease is, say, 1 in 10 000, then about 30% of ear, nose, and throat units could have a contaminated instrument set in the operating theatre.<sup>13</sup> This risk is likely to be increased as instruments tend to "wander" across to other instrument sets with time.

By contrast, patients undergoing lymph node excisions and neurosurgery are usually older and have generally shorter life expectancies. PrP<sup>Sc</sup> is expressed in neural tissue relatively late in the incubation period, and neurosurgical operations are performed on fewer patients. Compared with the population undergoing

adenotonsillectomy, these patients are likely to have a lower attributable risk.

The case for disposable instruments in appendicectomy remains less clear. So far, the evidence that the appendix is a reliable site for abnormal prion expression is weaker than for tonsils, with only a single case reported with positive immunohistochemistry. However, this operation shares many of the risk attributes of tonsillectomy in that the patient population is otherwise healthy and young and the operation is common.

The Department of Health has worked closely with the British Association of Otorhinolaryngologists-Head and Neck Surgeons to determine the feasibility of using disposable instruments for adenotonsillectomy and in implementing the changes. Although we cannot guarantee that the likely transmissible agent of vCJD will be completely eliminated by the proposed changes in decontamination of surgical instruments, any improvement on the present system is likely to reduce the potential infectious load. If the infectivity is dose related, then this generic approach, together with the specific use of disposable instruments for adenotonsillectomy, should reduce the attributable risk to the population, and is therefore welcome.

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AF was involved in developing the Exmoor disposable tonsillectomy kit, originally designed to confirm diagnosis of clinically suspected cases of vCJD in living patients by tonsil biopsy.

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